EXHIBIT 2

AMERICAN ARBITRATION ASSOCIATION
NEW YORK, NEW YORK

ACORDA THERAPEUTICS, INC.,	)	
	)	
Claimant,	)	
	)	
v.	)	Case No. 01-20-0010-8421
	)	
ALKERMES PLC,	)	
	)	
Respondent.	)	
	)	

AMENDED ANSWERING STATEMENT AND COUNTERCLAIMS BY RESPONDENT ALKERMES PLC

Dated: October 1, 2020

ALKERMES PLC,

By its attorneys,

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CONFIDENTIAL

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INTRODUCTION

1. Well before Acorda Therapeutics, Inc. ("Acorda") became involved, Alkermes Pharma Ireland Limited, a wholly-owned subsidiary of Alkermes plc, was engaged in significant development work for the product that would become AMPYRA® (fampridine). AMPYRA® is the first product approved by the FDA to improve walking speed in people with multiple sclerosis ("MS"), though it also competes with other MS drugs. Alkermes had virtually finalized the AMPYRA® formulation before Acorda even existed as a company, and thus before Acorda and Alkermes had begun even to discuss a partnership.[1]

2. Acorda and Alkermes began to collaborate in 1995, the year that Acorda was formed. This collaboration resulted in FDA approval of the New Drug Application ("NDA") for AMPYRA® in 2010. Sales of AMPYRA® began shortly after approval, with the product manufactured by Alkermes and marketed by Acorda. The NDA is in Acorda's name, and Acorda certainly made significant contributions to the product development, but the NDA also contains and relies on key contributions from Alkermes's development work. Acorda's attempt in these proceedings to portray Alkermes as merely a commercial partner or contract manufacturer could not be farther from the truth. Put simply, without the know-how and other contributions that Alkermes made, AMPYRA® would not have come into existence.

3. The license and supply agreements between Alkermes and Acorda that underly this dispute recognize the existence and value of Alkermes's contributions to AMPYRA®. *See* Amended and Restated License Agreement dated Sept. 26, 2003 (the "License Agreement", attached to the Demand as Exhibit A); Supply Agreement dated Sept. 26, 2003 (the "Supply Agreement", attached to the Demand as Exhibit B). Those agreements substantiate the value of Alkermes's patent rights (defined as "Elan Patent Rights", which includes both issued patents and patent applications), and provide that Acorda will pay royalties to Alkermes in return for the license Alkermes granted Acorda to those patent rights. The agreements separately substantiate the value of Alkermes's know-how (defined as "Elan Know-How", which includes Alkermes's knowledge, data, trade secrets, and expertise that Alkermes contributed to AMPYRA®), and separately provide that Acorda will pay a royalty to Alkermes for Acorda's use of that know-how. The agreements anticipate that the know-how royalties will continue if and when there comes a point when there are no continuing Elan Patent Rights and specifically set out the royalty rate that would apply in those circumstances. Together, these provisions required Acorda to make all the royalty payments it has made to date, and neither the agreements nor the patent-

[1] Elan Corporation, plc and its subsidiary, Elan Pharma International Limited, (together, "Elan") were the contracting parties with Acorda until September 2011, when the businesses of Alkermes, Inc. and the drug technologies business of Elan were combined under Alkermes plc. "Alkermes" will be used interchangeably throughout this Answer in reference to either Alkermes Pharma Ireland Limited, Alkermes plc's subsidiary that, as of and after September 16, 2011, acquired the Elan drug technologies business, Alkermes plc, or Elan, though to avoid confusion, the defined terms from the parties' agreements will be used, which often refer to "Elan."

misuse doctrine set out in *Brulotte* and *Kimble* on which Acorda relies provides any basis to conclude otherwise.[2]

4. In addition, in the Supply Agreement, the parties bargained for and agreed that Acorda would pay Alkermes a supply price calculated as 8% of Acorda's net selling price for the product that Alkermes manufactured and supplied to Acorda.

5. As recently as 2016, Alkermes and Acorda agreed to a five-year extension of these agreements, and further entered into additional agreements in 2018. When the parties entered into these agreements in 2016 and 2018, it certainly was foreseeable to both parties that generic versions of AMPYRA® might enter the market in the following few years; Acorda was already in patent litigation with numerous potential generic competitors. Even so, Acorda agreed to the contract extensions, including the royalty rates and the supply price, notwithstanding that the unambiguous terms of the agreements showed that those economic terms would continue in effect after generic entry, should it occur. In so doing, Acorda demonstrated its own understanding of the reasonableness of those provisions.

6. But now, through this arbitration, Acorda seeks to avoid its agreed-upon obligations to pay Alkermes the royalties required by their agreements for Acorda's past and ongoing use of Alkermes's intellectual property, and to impose a unilateral reduction in the price it pays Alkermes for the AMPYRA® that Alkermes manufactures for it. Acorda effectively seeks a windfall of tens of millions of dollars. Its arguments for that result are entirely meritless.

7. Acorda's basic argument about royalty payments boils down to two primary points, both of which fail. Acorda argues that:

   (a) it had no legal obligation to pay any royalties to Alkermes after July 30, 2018, when a patent assigned to Alkermes expired – despite the *ongoing* existence of *other* Elan Patent Rights, as well as the Elan Know-How, that both continue to require royalty payments; and

   (b) Alkermes should be required to refund back to Acorda all royalty payments it received from Acorda since July 30, 2018 – despite the provision in the agreement specifically stating that all royalty payments received by Alkermes from Acorda are *non-refundable* and governing New York law that applies the same rule.

   Acorda has no basis to stop paying royalties, let alone to force a refund of royalties already paid.

8. Acorda throws in an argument that Alkermes somehow has been engaged in monopolization since 2018 by continuing to abide by the agreements, including by charging the agreed-upon royalties and supply price. Those claims also fail. Among other things:

[2] *Brulotte v. Thys Co.*, 379 U.S. 29 (1964); *Kimble v. Marvel Entm't, LLC*, 576 U.S. 446 (2015).

(a) Any antitrust claim is frivolous, because competition has *increased* since 2018 due to the entry of several generics, and Alkermes affirmatively *helped* Acorda compete, including by licensing and supplying product that allowed Acorda to launch its own generic version of AMPYRA® while it continued to sell the branded presentation, thus maximizing revenues for Acorda and Alkermes alike.

(b) Acorda freely and voluntarily agreed to the 10% royalty in the 2003 License Agreement and the 8% supply price in the 2003 Supply Agreement, and did so again in 2016 and 2018, including regarding what Acorda would pay Alkermes for Acorda's own generic product.

(c) Acorda has had the right all along to terminate the license and supply agreements and seek supply from an alternate source, so Alkermes has in no way exercised some supposed monopoly power that coerced Acorda to continue to obtain supply from Alkermes. Indeed, Alkermes previously worked with Acorda to qualify an alternate supply source.

(d) At most, Acorda asserts a claim that *it* somehow has been harmed, but that alone fails to state a claim. Antitrust laws protect competition, not any individual competitor, and harm to Acorda alone does not suffice. Any suggestion that consumers have been harmed since 2018 is unsupportable in light of generic entry and the resulting availability of lower-priced alternatives.

Acorda thus has no basis for an order forcing Alkermes to supply product at prices lower than those the parties previously agreed to.

9. As a last-ditch effort, Acorda invokes the implied covenant of good faith and fair dealing, but its attempt to do so is equally misguided, improperly trying to use that doctrine to contravene the express terms of the agreements, a result that governing New York law forbids.

10. In summary, the plain terms of the parties' agreements, the remaining evidence, and applicable law all show that (a) Acorda had and continues to have a valid and enforceable obligation to pay royalties to Alkermes; (b) the supply price Acorda committed to pay Alkermes is fair, reasonable, and not subject to attack; (c) Acorda has made no "overpayments" to Alkermes, and Alkermes has not been unjustly enriched; (d) Alkermes has not violated the antitrust laws; and (e) Alkermes has breached neither the parties' agreements nor the covenant of good faith and fair dealing.

11. For these and the other reasons we explain in more detail below, Acorda's demand should be rejected in its entirety.

FACTUAL BACKGROUND

A. The Parties

12. Acorda Therapeutics, Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 420 Saw Mill River Road, Ardsley, New York 10502.

13. Alkermes PLC is an Irish public limited company having a principal place of business at Connaught House, 1 Burlington Road, Dublin 4, Ireland. Alkermes Pharma Ireland Limited is a subsidiary of Alkermes PLC, having the same principal place of business. Alkermes, Inc. is also a subsidiary of Alkermes PLC and has a principal place of business at 852 Winter Street, Waltham, MA 02451. In September 2011, the businesses of Alkermes, Inc. and the drug formulation and manufacturing business unit ("EDT") of Elan Corporation, plc were combined under Alkermes PLC. Elan is the predecessor in interest to Alkermes.

B. Alkermes's Development of Technology That Lead to AMPYRA® Prior to Its Relationship with Acorda

14. In 1990, Alkermes started work on the development of a 4-aminopyridine ("4-AP" or fampridine) product that would lead to AMPYRA®. At this time, Alkermes's work was in partnership with Rush-Presbytarian-St. Luke's Medical Center ("Rush"). Over the course of the next four years, Alkermes worked in three streams – toxicology, clinical development and formulation development.

15. In November 1990, Alkermes filed its first patent application, IE 3952-1990, the priority founding application for the patent family which includes US 5,540,938 (from USSN 07/786,400) and foreign equivalents.

16. Alkermes and Rush determined early on that a sustained-release approach would be necessary in light of potential adverse effects (such as seizures) from a spike in plasma concentrations arising from an immediate-release administration. Alkermes focused on two different dosage forms to achieve this goal of providing a sustained release of 4-AP in a capsule (the "SR-capsule"). By the mid-1990s, the oral route had been identified as the primary focus, and an SR-capsule formulation progressed to Phase II studies in MS patients. Alkermes adopted a development approach to identify the maximum tolerable dose. During the course of 1993, Alkermes conducted multiple studies with fampridine in MS patients including a dose-finding study in MS patients, a pharmacokinetic and tolerability study of single and multiple doses in patients, and a tolerability study of SR 4-AP in patients in December 1993.

17. By the end of 1993, concerns had arisen as to the stability of the SR-capsule formulation and whether it would be a viable commercial product. A search for an alternative dosage form commenced in earnest in early 1994, with the goal of finding a substitute with the same release profile as the SR-capsule but with better stability. By the end of 1994, Alkermes scientists' development work on the matrix tablet formulation was essentially

complete. The 4-AP matrix tablet, which arose from these efforts, is the dosage form ultimately commercialized in AMPYRA®.

18. It was only at this point in time, after Alkermes had spent years developing the fampridine product, including characterizing the active pharmaceutical ingredient, identifying and controlling impurities, developing a sustained-release formulation, and performing clinical studies, that first contact between Alkermes and Acorda occurred in December 1995. Acorda had just formed when Acorda's CEO and President, Ron Cohen, reached out to Alkermes, which led to a decades-long joint collaboration and series of agreements that continues to this day.

C. The Acorda-Alkermes Relationship

19. Alkermes has had a relationship with Acorda since Acorda's founding in 1995. As noted above, Acorda's Ron Cohen contacted Alkermes' business development team to discuss fampridine in December 1995. As a result of those discussions, the parties entered into a Letter Agreement, dated December 31, 1996. The parties entered into additional agreements which provided for the clinical development of Alkermes' fampridine matrix tablet formulation in both Spinal Cord Injury ("SCI") and MS, with both companies working in collaboration.

20. Alkermes (then Elan) and Acorda entered into a License and Supply Agreement on April 21, 1998, where Alkermes granted Acorda access to its patent rights and know-how, forming the foundation of the License and Supply Agreements that would continue in the decades to follow.

21. On September 26, 2003, the parties entered into the License Agreement and the Supply Agreement for AMPYRA®.

22. Subsequently, Acorda and Alkermes worked hand in hand to develop AMPYRA®, which has enhanced the lives of people suffering from MS.[3]

23. In the License Agreement, Alkermes granted Acorda exclusive worldwide rights to AMPYRA® for all indications, including SCI and MS. *See* Ex. A, Article 2.1.[4] In June 2009, Acorda and Alkermes amended their agreement, where Alkermes consented to Acorda's request for a sublicense to Biogen of Acorda's rights to use and sell AMPYRA® outside of the United States. AMPYRA® is marketed by Biogen as FAMPYRA® outside of the United States.

[3] Alkermes also worked together with Acorda's wholly-owned subsidiary, Civitas, in development and commercialization of ARCUS products, focused on pulmonary delivery systems, a technology platform designed to deliver medication through inhalation.

[4] Exhibit A is a reference to the License Agreement attached as Exhibit A to Acorda's Demand for Arbitration. Exhibit B is a reference to the Supply Agreement attached as Exhibit B to Acorda's Demand.

24. In the Supply Agreement, Alkermes agreed, at Acorda's request, to transfer the manufacturing process for AMPYRA® to a third party which would serve as a second source of the product. *See* Ex. B, Clause 7.

25. Since FDA approval in 2010, Acorda has acted as Alkermes's partner in selling AMPYRA® in the United States pursuant to the terms of the License Agreement. Likewise, since FDA approval, Alkermes has manufactured AMPYRA® for sale in the United States, and FAMPYRA® for sale internationally.

26. On January 14, 2011, Acorda entered into the Development and Supplemental Agreement to Amended and Restated License Agreement, dated 26 September 2003, as amended, and Supply Agreement for potential follow-on drugs to AMPYRA® (the "2011 Follow-On Drug Agreement").

27. Alkermes and Acord subsequently amended their relationship again in 2012 and 2013.

28. In 2016, Alkermes and Acorda agreed to a five-year extension of these agreements, including the same royalty and supply price terms in the License Agreement.

29. In anticipation of potential generic entry into the market, Acorda requested greater flexibility for the delivery of certain payments, which Alkermes agreed to in a Letter Agreement executed on June 22, 2018 ("2018 Letter Agreement"). In the 2018 Letter Agreement, Acorda again specifically recommitted itself to the royalty and supply price terms in the License Agreement.

30. On July 19, 2018, Alkermes entered into a Consent to Sublicense agreement with Acorda to allow for Acorda to sell an authorized generic ("AG") version of AMPYRA®, working with a generic drug company called Mylan Pharmaceuticals, Inc. ("Mylan"). In that agreement, Acorda again committed to paying license rates specified in the License Agreement and no less than the supply price specified in the Supply Agreement. The parties amended this agreement in the Amended and Reinstated Consent to Sublicense on August 15, 2018.

D. The License Agreement

31. In the License Agreement, Alkermes granted Acorda exclusive licenses to certain of Alkermes's patent rights and know-how, in return for Acorda's obligations to pay royalties to Alkermes. The licenses apply to AMPYRA®, and Acorda is required to pay Alkermes royalties with respect to AMPYRA®. Both the scope of the licenses and the structure of the various royalty obligations are more complex than Acorda portrays. These details matter, because they highlight many of the fallacies in Acorda's positions.

i. Alkermes Intellectual Property Licensed to Acorda that Applies to AMPYRA®

32. Pursuant to the License Agreement, Alkermes granted Acorda an exclusive license for "Elan Intellectual Property." *See* Ex. A, Article 2.1. "Elan Intellectual Property" is defined

as both "the Elan Patent Rights and/or the Elan Know-How." *See id.* Article 1.1 (Definitions).

33. Both "Elan Patent Rights" and "Elan Know-How" are defined in relation to the "Product." The relevant patent rights includes those "which would be infringed by the manufacture, use or sale of the Product," and the know-how includes proprietary information "relating to the Product." *See id.* Article 1.1 (Definitions).

34. "Product" is defined as "any finished pharmaceutical dosage form containing the Compound or an Alternate Compound, which is in the scope of one or more Valid Claims within the Elan Patent Rights in the country of sale, and/or incorporates Elan Know-How in material part." *See id.* Article 1.1 (Definitions).

35. "Compound" is defined as "the compound known as 4-aminopyridine as well as the isomers, and the salts thereof." *See id.* Article 1.1 (Definitions).

36. AMPYRA® is a Product as defined in the License Agreement.

37. The licenses that Alkermes granted Acorda to the Elan Intellectual Property apply to AMPYRA® and Acorda's sale of AMPYRA®.

ii. Alkermes's Patent Rights Licensed to Acorda for AMPYRA®

38. As part of the License Agreement, Alkermes licensed the "Elan Patent Rights" to Acorda.

39. "Elan Patent Rights" is defined as "any and all rights under any and all patents and patent applications now existing, currently pending or hereafter filed, owned or acquired or licensed by Elan (and/or its Affiliates) which would be infringed by the manufacture, use or sale of the Product, the current status of which as of the Amendment Date is set forth in Schedule 3. Elan Patent Rights shall also include all continuations, continuations-in-part, divisionals and re-issues of such patents and patent applications and any patent issuing thereon and extensions of any patents licensed hereunder. Elan Patent Rights shall further include any patents or patent applications covering any improved methods of making or using the Product invented or acquired by Elan (and/or its Affiliates) during the term of this Agreement and under which Elan (and/or its Affiliates) has a right to grant a licence hereunder, and Elan's (and/or its Affiliates) ***interest in any intellectual property conceived reduced to practice or otherwise developed in connection with the Project***." *See id.* Article 1.1 (Definitions) (emphasis added).

40. Schedule 3 to the License Agreement sets out a non-exhaustive list of Elan Patent Rights that were in existence as of the time of the Agreement.

41. Some, but by no means all, of the Elan Patent Rights include certain patent claims that were invalidated or expired in 2018. On July 30, 2018, Alkermes's U.S. Patent No. 5,540,938 ("the '938 patent") expired. However, claims of at least four of the patents comprising the Elan Patent Rights—although currently assigned to Acorda rather than Alkermes—remain valid and unexpired: U.S. Patent Nos. 8,007,826 ("the '826 patent");

8,663,685 ("the '685 patent"); 8,354,437 ("the '437 patent"); and 8,440,703 ("the '703 patent") (together, the "Unexpired Patents"). Although certain claims of the Unexpired Patents were invalidated,[5] each of the Unexpired Patents still has valid claims.

42. As explained *infra* at Paragraphs 85-101, the Unexpired Patents constitute part of the Elan Patent Rights because they each claim priority to a patent application which was filed by Acorda, but in which Alkemes has an "interest" because it was "conceived[,] reduced to practice or otherwise developed in connection with the Project" with the help of at least one uncredited Alkermes employee. *See* Ex. A, Article 1.1. The '826 patent and the '685 patent are also part of the Elan Patent Rights for the additional reason that they claim priority to three provisional patent applications which were filed and owned by Alkermes, and in which Alkermes has an "interest." *See id.* (defining the Elan Patent Rights to include "any and all rights under any and all . . . patent applications . . . hereafter filed[or] owned . . . by Elan . . . which would be infringed by the manufacture, use or sale of the Product. . . . Elan Patent Rights shall also include all continuations, continuations-in-part, divisionals and re-issues of such . . . patent applications *and any patent issuing thereon*. . . .") (emphasis added).

iii. Alkermes's Know-How Licensed to Acorda for AMPYRA®

43. Separate and apart from the licensed Elan Patent Rights, Alkermes also granted Acorda a license to the Elan Know-How. In the license agreement, Acorda acknowledged the separate existence and separate value of this know-how.

44. "Elan Know-How" is defined as "all knowledge, information, trade secrets, data and expertise within Elan's oral controlled release technology relating to the Product which is not generally known to the public that is owned or possessed by Elan (and/or its Affiliates), or to be developed by Elan (and/or its Affiliates), whether before or during the term of this Agreement, whether or not covered 'by any patent, copyright, design, trademark or other industrial or intellectual property rights . . . .'" *See id.* Article 1.1 (Definitions).

45. There are at least three categories of valuable Elan Know-How.

46. ***First***, Elan Know-How comprises manufacturing pharmaceutical grade fampridine, AMPYRA®'s active pharmaceutical ingredient ("API"), including impurity profile details for fampridine as well as methods for determining impurity levels in a particular sample of fampridine (the "Impurity Know-How"). Because AMPYRA® is the first drug to use fampridine as its API, there were no industry accepted methods available for producing pharmaceutical-grade fampridine or determining impurity levels in fampridine when Alkermes began working with the molecule. Alkermes developed proprietary, validated

[5] In *Acorda Therapeutics, Inc. v. Roxane Laboratories, Inc.*, the Federal Circuit affirmed the invalidation for obviousness of claims 1, 7, 38, and 39 of the '826 patent; claims 3 and 5 of the '685 patent; claims 1, 2, 5, 22, 32, 36, and 37 of the '437 patent; and claims 36, 38, and 45 of the '703 patent. 903 F.3d 1310, 1327, 1342 (Fed. Cir. 2018).

methods for confirming the purity of fampridine and identified specific impurities likely to result from the API manufacturing process.

47. ***Second***, Elan Know-How includes the discovery that drug substance particle size is critical to achieving content uniformity of the AMPYRA® drug blend prior to compression into a tablet (the "Tablet Know-How"). Tablet uniformity is particularly important in a sustained release formulation, such as AMPYRA®, because it is needed to ensure that the right dose is released at the right rate to the patient in order to achieve the right concentration of drug and efficacy in the patient. The Tablet Know-How also includes the extensive investigations and optimization of tablet hardness which Elan conducted to ensure stability.

48. ***Third***, Elan Know-How includes solutions to the significant challenge of controlling the amount of moisture in AMPYRA® tablets (the "Moisture-Control Know-How"). The presence of excess moisture in tablets was hypothesized as a cause of API degradation for fampridine. Alkermes undertook extensive work to address this problem during both product development and commercial manufacturing. One moisture mitigation approach developed by Alkermes was to optimise the coating conditions for applying the cosmetic coating so as to minimise moisture content of the finished tablets.

49. The Elan Know-How remains strictly confidential. For example, when Acorda selected Patheon Inc. ("Patheon") as its Second Supplier of AMPYRA® (*see infra* ¶¶ 65-66) and Alkermes transferred the Elan Know-How to Patheon to effectuate their manufacturing capabilities, Alkermes imposed an obligation of confidentiality on Patheon. *See* Ex. B, Clause 7.1.

iv. Acorda's Royalty Obligations to Alkermes for AMPYRA®

50. In exchange for the licenses Alkermes provided Acorda to the various aspects of the Elan Intellectual Property, the License Agreement requires Acorda to pay royalties to Alkermes. The License Agreement contains a number of separate royalty provisions, which set out separate royalty obligations to separate pieces of the Elan Intellectual Property and which apply in varying circumstances. Those various royalty obligations are contained in Article 5 of the License Agreement, titled "Financial Provisions." Some of the royalties apply solely for the license to Alkermes's patent rights. Another provision specifies the royalties that Acorda must pay on sales of AMPYRA® for both Alkermes's patent rights, when any are still in effect, and for Alkermes's know-how. Yet another provision specifies the royalties that Acorda must pay on sales of AMPYRA® for Alkermes's know-how, even when there are no longer any remaining applicable Alkermes patent rights.

51. Acorda has been, and remains, required to pay Alkermes royalties under these provisions.

a. Royalties specific to Elan Patent Rights alone

52. Certain of Acorda's royalty obligations derive solely from its license to the Elan Patent Rights. Specifically:

- Article 5.2, titled "License Royalties," includes a lump upfront payment "[i]n consideration of the rights and license granted to Acorda to the Elan Patent Rights."

- Article 5.3, titled "Milestone Payments," includes specific enumerated payments from Acorda triggered by specific events in "consideration of the rights and license granted to Acorda to the Elan Patent Rights."

No part of the royalty payments required by Articles 5.2 or 5.3 are for the separate license to the Elan Know-How.

53. Article 5.5, titled "License Revenues," states that Acorda must pay Alkermes 7% of License Revenues in "consideration of the rights and licence granted to Acorda to the ***Elan Patent Rights***." (emphasis added).

b. Royalties on sales based on licensed Elan Patent Rights (when still in effect) and Elan Know-How

54. Article 5.6.1 sets out an additional "Royalty on Sales" Acorda must pay Alkermes (a) when there are valid claims under the Elan Patent Rights,[6] and (b) for the Elan Know-How. The royalty in those circumstances is 10% of the Net Selling Price ("NSP")[7] for product sales. This additional royalty payment is in "consideration of the rights and license granted to Acorda to the ***Elan Patent Rights*** while there is a Valid Claim thereunder, ***and*** in consideration of the rights and license granted to Acorda of the ***Elan Know-How thereafter***." (emphasis added.)

55. Acorda has exclusive control over the NSP for AMPYRA®. Given that the royalty on sales is calculated as a percentage of NSP, Acorda ultimately controls the absolute value of the royalty on sales it is required to pay Alkermes.

56. Alkermes continues to have Valid Claims under the Elan Patent Rights, as discussed above, and Elan Know-How.

c. Royalties on sales based on licensed Elan Know-How alone

57. Article 5.6.2 separately sets out the royalty Acorda must pay Alkermes on sales of AMPYRA® based on the license to the Elan Know-How if and when there comes a time when there are no longer any applicable claims under the Elan Patent Rights that support a patent-based royalty (*i.e.,* there are no remaining Valid Claims). The royalty in those circumstances is 10% of the NSP for AMPYRA®.

[6] "Valid Claim(s)" is defined as "a claim in any patent within the Elan Patents which has not lapsed or become abandoned and which claim has not been declared invalid by an unreversed or an unappealable decision of a court of competent jurisdiction." Ex. A, Article 1.1.
[7] NSP is defined in Article 1.1.

58. Also per Article 5.6.2, the royalty would drop to 4.25% upon the occurrence of three pre-conditions, but those conditions have not all occurred as of the date of this filing, so the 10% royalty rate continues to apply.[8]

v. Acorda's Royalty Payments to Alkermes Are Non-Refundable

59. Article 5.8 provides, "All payments received by Elan from Acorda under Article 5 shall be non-refundable, subject to the provisions of Article 5.9.5."

60. Article 5.9.5 is an audit provision providing each party the right to have its accountants review the other's books and records "solely for the purpose of verifying the accuracy and reasonable composition of the calculations hereunder for the calendar year then ended, including in the case of [Alkermes] the sums payable by Acorda to [Alkermes] pursuant to Article 5."

vi. Other Provisions of the License Agreement

61. Article 12.5.2.1 states, "Acorda may terminate this Agreement in its entirety . . . with ninety (90) days prior written notice to Elan."

62. The License Agreement is governed by the laws of the State of New York. *See* Ex. A, Article 12.11.

E. The Supply Agreement

63. Under the Supply Agreement, Alkermes agreed to manufacture and supply AMPYRA® for Acorda.

64. The Supply Agreement is exclusive, barring Alkermes from supplying AMPYRA® to any seller other than Acorda outside of the Elan Territory. *See* Ex. B, Clause 2.2.1.

65. While Alkermes is not permitted to supply parties other than Acorda, Acorda is permitted under the Supply Agreement to use Patheon as its second source of the product. *See id.* Clause 7.1. The Supply Agreement limits the amount of AMPYRA® Acorda may purchase from Patheon in any given year, except in the event of a "Serious Failure to Supply" by Alkermes, as defined in Clause 1.1.

66. In order to facilitate Patheon's ability to act as second source of the product, Alkermes undertook what is known as a "tech transfer" to Patheon, which allowed Patheon to become approved by the FDA as another site where AMPYRA® can be manufactured under the AMPYRA® NDA. *See id.* Clause 7.1.4.

[8] The three conditions are: (1) Alkermes no longer manufactures the Product; (2) there are no remaining Valid Claims; and (3) the sales or distribution of a sustained release oral pharmaceutical for treatment of amelioration of any neurological condition by a Third Party for a calendar year are at least fifteen per cent (15%) of the total sales of the Product in the country where the Third Party's product is sold.

67. In exchange for this manufacturing exclusivity, Acorda has agreed to pay Alkermes 8% of the NSP for product sales, subject to discounts in certain circumstances (the "Supply Price"). *See id.* Clause 9.3.1.

68. The Supply Price is controlled and determined by Acorda at its sole discretion, as is the end market price.

69. The Supply Agreement will expire upon expiry or termination of the License Agreement. *See id.* Clause 11.1.

F. AMPYRA® and the Market at Large

70. AMPYRA® is one of many disease modifying medications in the MS market. This market also includes Tecfidera and Copaxone, among other products. Neither Alkermes nor AMPYRA® has monopoly power in the MS market.

71. However, even looking just at sales of AMPYRA® and its equivalents (as Acorda attempts to define "Market"), the market is highly competitive. In 2018, several generic versions of AMPYRA® entered and have since captured roughly 80% of total sales by volume. Such generic conversion is common upon generic entry in the pharmaceutical industry. The generics sell at prices that are substantially lower than the prevailing prices for brand AMPYRA® prior to generic entry.

72. Notwithstanding generic entry, Alkermes continues to manufacture AMPYRA® for Acorda, and Acorda continues to market AMPYRA® in the United States.

73. Today, at least one third party has held more than 15% market share of the AMPYRA® market for a full calendar year, meaning there is Competition as defined in the License Agreement. *See* Ex. A, Article 1.1 (Definitions).

74. Acorda has been successful competing against generic versions of AMPYRA®. As one example, Acorda has retained approximately 20% by volume of total brand-plus-generic sales of AMPYRA®, which is relatively high for a brand facing multiple generic entrants. Alkermes has actively facilitated Acorda's efforts to compete in the face of generic entry.

75. Alkermes assisted Acorda in launching an Authorized Generic ("AG") version of AMPYRA® – that is, the brand product manufactured under the NDA but sold in a generic presentation – to allow AMPYRA® to further compete with the Abbreviated New Drug Application ("ANDA") generics. Acorda chose to market the AG through a generic company called Mylan. To facilitate Mylan's entry into the market, Alkermes also agreed to allow Acorda to take product Alkermes had manufactured to be sold as brand – at higher prices, which would therefore generate higher royalties for Alkermes – and have that product repackaged to be sold by Mylan as AG product. Mylan launched the AG in 2018 and made substantial sales.

76. Acorda recently chose not to renew its AG agreement with Mylan.

77. Alkermes also helped Acorda with the impending emergence of generic entry by entering into the 2018 Letter Agreement. Acorda approached Alkermes for help due to uncertainty about how much brand product it would be able to sell and in what timeframe, depending on how the Federal Circuit would rule and whether generics would enter. *See* 2018 Letter Agreement § 1. Alkermes agreed to help by agreeing to delay when royalties would actually be paid for up to 5 batches.

G. Attempts to Resolve this Dispute

78. Acorda's President and CEO, Ron Cohen, reached out to Richard F. Pops, Alkermes's CEO, in December 2019 to discuss royalties, expressing a desire to have the Elan Royalty under the License Agreement lowered. Mr. Pops offered that Dr. Cohen or an employee of Acorda reach out to Alkermes's head of business development to discuss this matter further.

79. It appeared the discussions ended there, as Acorda did not reach out again for four months. On April 22, 2020, Dr. Cohen wrote Mr. Pops a letter where he admitted to recently discovering the existence of a Supreme Court case, *Brulotte v. Thys Co.* (discussed below), claiming it made the continuation of a 10% royalty rate for US sales unenforceable.

80. Over the next few months, personnel from Acorda and Alkermes attempted to engage in negotiations, but they did not prove fruitful. Acorda refused to acknowledge the value of Elan's Know-How, despite previously admitting it had value in public filings in other matters.

81. On July 10, 2020, Acorda sent Alkermes a notice for arbitration. Acorda filed its arbitration demand on July 28, 2020.

RESPONSE TO ACORDA'S CLAIMS – THEY ALL FAIL

82. Nothing in the actual agreements that Acorda signed with Alkermes provides any basis for the relief Acorda seeks. On their face, the agreements required Acorda to make all the royalty and supply price payments it has made to Alkermes, and those agreements require Acorda to continue to do so unless and until they are terminated. Acorda does not even attempt to argue otherwise. Acorda therefore resorts to extra-contractual arguments in its efforts to escape its obligations. Primarily, Acorda relies on patent-misuse arguments grounded in *Brulotte* and *Kimble*, but for a variety of reasons that doctrine provides Acorda no help in avoiding its contractual agreements. That should be the beginning and the end of this dispute. Acorda's additional arguments under antitrust and the implied covenant are make-weights that utterly fail to support the relief Acorda requests.

83. In the remainder of this Answer we discuss numerous independent reasons why Acorda's claims all fail. To summarize:

A. There is no patent misuse under *Brulotte* because Alkermes still has Valid Claims under the Elan Patent Rights that support the payment of patent royalties on ongoing sales. By definition, therefore, there can be no extension of Alkermes's

patent rights beyond their term, which is the necessary predicate for patent misuse under *Brulotte*.

B. Even if there were no Valid Claims after July 30, 2018, there is still no patent misuse under *Brulotte*, because the doctrine permits Alkermes to charge royalties for non-patent rights such as the Elan Know-How, and the structure of the royalties for the license to the Elan Know-How is entirely permissible under *Brulotte* and otherwise.

C. Even if there were somehow a *Brulotte* violation after July 30, 2018, it would provide no basis to compel a refund of any royalties Acorda already paid. At most, *Brulotte* would apply to prevent Alkermes from enforcing the license agreement to collect royalties in the future. Cases have consistently held that *Brulotte* provides no basis to require refunds of royalties already paid, New York's "voluntary payment doctrine" similarly bars any claim for refunds in this context, and the License Agreement itself does as well.

D. Acorda's antitrust claims fail for a number of independent reasons, including the threshold issues that Alkermes has no monopoly power in a properly defined market and Alkermes has engaged in no exclusionary conduct. More generally, Alkermes has *helped* Acorda compete, rather than restricting competition. Acorda has always been free to terminate its agreements with Alkermes, so they cannot be said to restrain or coerce Acorda. And, at most, Acorda could only show harm to itself, not to competition or consumers.

E. Acorda's claim under the implied covenant fail because Acorda seeks to use that doctrine to contradict the express terms of the parties' agreements, which the law forbids.

F. Acorda's claim for attorneys' fees is barred by the arbitration provision in Article 12.14 of the License Agreement, which provides that "each party shall bear its own costs and attorneys' and witness' fees incurred in connection with the arbitration."

Acorda therefore should be denied all of the remedies it requests.

A. There is no patent misuse under **Brulotte** *because there are still Valid Claims that support payment of patent royalties.*

84. The *Brulotte* rule of unenforceability only comes into play upon "a patentee's use of a royalty agreement that projects beyond the expiration date of the patent." *Brulotte*, 379 U.S. at 32. When multiple patents are involved, there can be no patent misuse under *Brulotte* so long as that patentee continues to hold at least some patent rights during the period for which it charges royalties, even if other patents had expired earlier. *See Kimble*, 576 U.S. at 454 ("[R]oyalties may run until the latest-running patent covered in the parties' agreement expires.") (citing *Brulotte*, 379 U.S. at 30). Here, there are Valid Claims of Elan Patent Rights which support Acorda's continued obligation to pay royalties unchanged from 2018 and into the future. Thus, there can be no violation under *Brulotte*, the royalty

obligations remain enforceable, Acorda has no basis to avoid them, and it made no "overpayments" to Alkermes.

85. As noted above, "Elan Patent Rights" is broadly defined in the License Agreement and includes:

(1) "any and all rights under any and all patents and patent applications now existing, currently pending or hereafter filed, owned or acquired or licensed by Elan (and/or its Affiliates) which would be infringed by the manufacture, use or sale of the Product;"

(2) "all continuations, continuations-in-part, divisionals and re-issues of such patents and patent applications and any patent issuing thereon and extensions of any patents licensed hereunder;"

(3) "any patents or patent applications covering any improved methods of making or using the Product invented or acquired by Elan (and/or its Affiliates) during the term of this Agreement and under which Elan (and/or its Affiliates) has a right to grant a license hereunder;"

(4) "Elan's (and/or its Affiliates) interest in any intellectual property conceived reduced to practice or otherwise developed in connection with the Project." *See* Ex. A, Article 1.1 (Definitions).

86. Alkermes continues to have Valid Claims in Elan Patent Rights for several reasons.

87. ***First***, Alkermes has rights to and an interest in the Unexpired Patents, which contain Valid Claims under the terms of the License Agreement.

88. The Unexpired Patents and other Acorda patent applications originate from Alkermes patent applications, but Acorda did not credit Alkermes's contributions to these patents and patent applications. Instead, Acorda purposefully, and impermissibly, removed Alkermes employees from inventorship. Regardless of Acorda's misconduct in changing inventorship, Alkermes has an interest in the patent application which demonstrates the continued existence of Elan Patent Rights.

89. On December 11, 2003, Alkermes filed three provisional patent applications describing the sustained release formulations of fampridine and their properties that had been discovered and developed by Alkermes during the Project: U.S. Serial Nos. 60/528,760 ("the '760 Application"), 60/528,592, and 60/528,593 (collectively, the "Alkermes Applications"). The Alkermes Applications contained descriptions of the contents of sustained release fampridine formulations, including the matrix tablet formulation, and the pharmacodynamic properties of those tablets in a range of doses, including the 10 mg dose that became AMPYRA®. The Alkermes Applications also contained data and information from Alkermes development reports demonstrating the efficacious use of sustained release compositions of fampridine to treat neurological conditions, such as MS and SCI, which Alkermes scientists had discovered in their formulation work with fampridine. The

Alkermes Applications identified as the named inventor Sean Cunningham, an Alkermes formulation scientist who worked on the development of AMPYRA®. In addition, Seamus Mulligan and Michael Myers worked on the Alkermes Applications and thus should also be considered inventors.

90. On April 9, 2004, Acorda filed a provisional application with U.S. Serial No. 60/560,894 ("the '894 Application"). The '894 Application was a nearly verbatim copy of the '760 Application that had been filed by Alkermes. Specifically, the '894 Application included the descriptions of the sustained release tablets of fampridine and their pharmacodynamic properties that had been developed at Alkermes, and copied from the Alkermes Applications the information that had been sourced from Alkermes development reports. The only additional material in the '894 Application is descriptions of clinical studies and the results of using the Alkermes sustained-release fampridine compositions in patients with MS and SCI. Nonetheless, the '894 Application did not credit Alkermes's Sean Cunningham as an inventor. The '894 Application also did not credit Alkermes's Seamus Mulligan or Michael Myers as inventors. Instead, it named only Acorda's Andrew Blight and an unspecified "et al." as inventors.

91. On December 13, 2004, Acorda consolidated the information and contents of the '894 Application and the Alkermes Applications into a single application by filing U.S. Patent Application No. 11/010,828 ("the '828 Application"). Acorda acted under its contractual responsibility to prosecute Joint Inventions,[9] and identified both Sean Cunningham of Alkermes and Andrew Blight of Acorda as inventors. The '828 Application claimed priority to the '894 Application and the Alkermes Applications. The claims submitted for prosecution with the '828 Application were directed to sustained release compositions of fampridine, their pharmacodynamic properties, and methods of using those sustained release compositions of fampridine for the treatment of neurological disorders, such as MS and SCI, and their clinical manifestations, such as walking.

92. During prosecution, Acorda unilaterally—and without Alkermes' knowledge—removed Sean Cunningham as an inventor, which deprived Alkermes of its inventorship and ownership rights in any patents issuing from the '828 Application, such as the '826 patent, thereby leaving Andrew Blight, an Acorda employee, as the sole inventor. Acorda subsequently added Acorda's President and CEO, Ron Cohen, as a joint inventor.

93. As noted above, the '826 patent issued from the '828 Application, which was originally filed under the names of both Alkermes and Acorda inventors. The issued claims of the '826 patent are directed to "Sustained Release Aminopyridine Composition[s]." For example, representative claim 36 of the '826 patent is directed to:

> A method to improve walking in a patient with multiple sclerosis in need thereof by use of a **sustained release composition** of 4-aminopyridine, where sustained indicates that **the composition achieves an in vivo 4-aminopyridine**

[9] "Joint Inventions" is defined in the Agreement as "all inventions and other intellectual property made jointly by employees of Acorda and Elan in connection with the Project, which inventions and intellectual property shall be owned jointly by Elan and Acorda." Ex. A, Article 1.1.

> **C_{maxSS}:C_{minSS} ratio of 1.0 to 3.5 and a C_{avSS} of 15 ng/ml to 35 ng/ml in a human**, said method comprising: orally administering twice daily for one day to the patient an amount of the sustained release composition having only 10 milligrams of 4-aminopyridine; and thereafter, maintaining twice daily administration of 4-aminopyridine by orally administering to said patient an amount of the sustained release composition having only 10 milligrams of 4-aminopyridine for a time period of at least two weeks.

(emphases added).

94. As set forth above, it was Alkermes that independently developed the sustained release compositions of fampridine which have the critical pharmacodynamic parameters set forth in the claims. Indeed, the data and written description support for these claims appears in the Alkermes Applications which named Alkermes employee Sean Cunningham as an inventor, and there is no question that Alkermes employees conceived of and reduced to practice the sustained release compositions that are the subject of the '826 patent claims and other claims of the Unexpired Patents. *See, e.g.,* '826 patent, cl. 2-3, 5-6, 8, 10-37, 40-41; '685 patent, cl. 1-2, 4, 6-8; '437 patent, cl. 3-4, 6-21, 23-31, 33-35, 38-40; '703 patent, cl. 1-35, 37, 39-44, 46-52.

95. Nor should there be any question that Alkermes employees invented the sustained release fampridine formulations of the Unexpired Patents. In fact, Acorda is currently engaged in prosecuting a related application to the '828 Application directed solely to sustained release compositions of fampridine and has identified there only Alkermes inventors, who have assigned their rights to Alkermes. *See, e.g.*, U.S. Application No. 16/695,024.

96. Accordingly, Alkermes has an interest in the Unexpired Patents. Because the Unexpired Patents are based on the disclosures and inventions of the Alkermes Applications, they constitute part of the Elan Patent Rights, regardless of their current assignee.

97. Moreover, because all of the Unexpired Patents originated with the '894 Application, and Alkermes has an "interest" in the '894 Application due to the uncredited contributions its employee made to the conception and reduction to practice of the '894 Application, all of the Unexpired Patents constitute part of the Elan Patent Rights.

98. Because several claims of the Unexpired Patents remain valid, and would be infringed "by the manufacture, use or sale of the Product," Elan Patent Rights continue to exist.

99. ***Second***, and notwithstanding Acorda's bad faith conduct in unilaterally removing Alkermes' inventors from the application, Alkermes also has an interest in at least two of the Unexpired Patents, the '826 patent and '685 patent, because Alkermes "filed[and owned]" the Alkermes Applications, which Acorda is relying on for priority. *See* Ex. A, Article 1.1. Specifically, the '826 patent and '685 patent claim priority to the '828 Application, which was based on the Alkermes Applications and claimed priority thereto. Acorda was only permitted to rely on the information contained in the Alkermes Applications and claim priority to them because of the licensed Elan Patent Rights. Stated otherwise, Acorda has Valid Claims in the '826 patent and the '685 patents solely by virtue

of the rights to the Alkermes Applications that Acorda licensed. These constitute Elan Patent Rights under the License Agreement.

100. ***Finally***, as set forth above, there can be no doubt that Alkermes's contributions to the Unexpired Patents constitute Elan Patent Rights as an "interest in any intellectual property conceived reduced to practice or otherwise developed in connection with the Project." *Id.* Article 1.1. All but a few examples in the Unexpired Patents came from Alkermes development work. In addition, the sustained release formulations that are the subject of the claims of the Unexpired Patents were conceived and reduced to practice by Alkermes employees and developed by Alkermes "in connection with the Project." Even Acorda employees have admitted that Acorda had no input on formulation development. Alkermes therefore has Valid Claims in all of the Unexpired Patents.

101. If it could not be more clear that Alkermes continues to have Valid Claims under its Elan Patent Rights, Acorda's ongoing patent prosecution strategy further validates that point. Indeed, Acorda continues to prosecute patent applications underlying AMPYRA® that stem from the '828 Application. U.S. Application No. 16/695,024 is one in a series of patent applications and lists three Alkermes inventors as the sole inventors. This patent application falls within the definition of Elan Patent Rights. Therefore, these patent applications alone would ensure that AMPYRA® is still royalty bearing due to Elan Patent Rights licensed by Alkermes to Acorda. It is contradictory for Acorda to allege patent misuse while at the same time seeking to extend patent protection to technology owned by Alkermes.

102. Because there are still Valid Claims, the Elan Royalty Rate of 10% has been and is correctly paid to Alkermes.

B. There is no patent misuse under* Brulotte *because the ongoing license to the Elan Know-How provides ample basis for all royalties post July 30, 2018.

103. Even if it was determined that there were no Valid Claims after July 2018, the requirement that Acorda continue to pay royalties would not constitute patent misuse under *Brulotte*. All royalties Acorda paid – and was required to pay – to Alkermes after July 2018 have been fully supported by the license and royalty provisions applying to the Elan Know-How.

104. The parties specifically contemplated, and agreed in Article 5.6.2 of the License Agreement, that Acorda would continue to pay know-how royalties even after any applicable patent rights ceased to exist. That type of agreement is entirely permissible. The Supreme Court reiterated in *Kimble* that, under the analysis dictated by *Brulotte*, "post-expiration royalties are allowable so long as tied to a non-patent right – even when closely related to a patent." 576 U.S. at 454. Here, all royalties Acorda paid after July 30, 2018 were tied, at a minimum, to non-patent rights: Acorda's ongoing license to the Elan Know-How. That license provides an ample independent basis for the requirement that Acorda pay royalties to Alkermes, fully consistent with *Brulotte,* even if there were no ongoing Valid Claims.

105. To the extent Acorda's argument relies on its assertion that there is a lack of step down in the royalty rate after all Valid Claims purportedly ceased in 2018, and that the royalty rate remains the same (10% of NSP) whether there are Valid Claims or not, that argument fails, for two reasons.

106. ***First***, the plain terms of the License Agreement make clear that the royalty Acorda pays for the Elan Patent Rights is *not* the same as the royalty it pays for the Elan Know-How; the patent royalty indisputably is higher. As discussed above, the royalty Acorda pays on the Elan Patent Rights includes three components: (i) the one-time lump-sum payment in Article 5.2; (ii) the milestone payments in Article 5.3; and (iii) the royalty on sales in Article 5.6.1. By contrast, the only royalty Acorda pays on the Elan Know-How is the royalty on sales in Article 5.6.2. Thus, even though the stated royalty rate for the royalty on sales is the same 10% of NSP for both the patent and know-how rights, the aggregate effective royalty rate for the patent rights is higher, because it also incorporates the additional royalty payments in 5.2 and 5.3, which apply *only* to the patent license. As a factual matter, therefore, Acorda's argument is simply wrong.

107. ***Second***, there is no absolute requirement that a post-patent-expiry royalty rate solely on non-patent rights must be lower than the royalty rate that applied prior to patent expiry. To the contrary, "a discounted rate may not be necessary to avoid *Brulotte* [when there is] some other clear indication that the royalty [due after patent expiry] was is no way subject to patent leverage." *Kimble v. Marvel Enters. Inc.*, 727 F.3d 856, 865 (9th Cir. 2013), *aff'd sub nom. Kimble v. Marvel Entm't, LLC*, 576 U.S. 446 (2015). If "the parties explicitly indicate[], in a separate section of the agreement, that royalty payments for sales of non-patent products . . . were to be paid . . . , it would arguably be immaterial if the rate were the same as the rate for sales of allegedly patent-infringing products." *Id.* at 865 n.5.

108. Here, the license agreement has separate sections for royalties on sales. One section sets out the running royalty due when there are both Valid Claims and Elan Know-How (Article 5.6.1), and another sets out the running royalty for Elan Know-How when there are no Valid Claims (Article 5.6.2). This is exactly the agreement structure that the Ninth Circuit recognized in *Kimble* as being permissible—*i.e.*, not creating a *Brulotte* problem—even if the royalty due in the two scenarios is the same. By clearly and separately articulating that the royalty on sales for the license to the Elan Know-How will be 10% even when there are no Valid Claims, the License Agreement shows that there was no improper leverage here, and thus there is no basis for finding the royalty unenforceable.

109. Acorda also argues that the Elan Know-How cannot justify Acorda's ongoing royalty obligations because there is nothing of continuing value. This argument is nothing short of remarkable. Elan Know-How is valuable and continues to exist, consisting of trade secrets and confidential commercial information, among other things.

110. Acorda's own actions over the years conclusively belie Acorda's new litigation-inspired position. Among other things:

A. Acorda is a sophisticated company that negotiated an original agreement in 1998 and then an amended agreement in 2003. In the course of doing so, Acorda clearly

must have recognized that the terms called for it to pay a know-how royalty calculated as 10% of NSP even after all patent claims expire. It would not have done so had it believed, as it now claims, that the know-how had zero independent value. Just the opposite: Acorda's repeated willingness to accept those contract terms shows that Acorda recognized the existence and independent value of the know-how.

B. Acorda again acknowledged the independent value of the Elan Know-How when it paid valuable consideration for a license to the Elan Know-How in order to develop a potential follow-on drug to AMPYRA®. On January 14, 2011, Acorda entered into the 2011 Follow-On Drug Agreement. Clause 4.7 of the Follow-On Drug Agreement granted Acorda a transferable license to the Elan Know-How (referred to as the "Compound Know-How and First Product Know-How") in the event that Acorda decided to develop a follow-on drug to AMPYRA® with a partner *other than Alkermes*, indicating that Acorda believed the Elan Know-How would be needed by any third-party manufacturer working with 4-AP. The Follow-On Drug Agreement provided for substantial royalties to Alkermes in the event that Acorda chose a partner other than Alkermes: "in consideration of [Alkermes]'s agreement to permit Acorda to commercialize [a follow-on drug with an entity other than Alkermes, under certain conditions] *and in consideration of the grant of the Compound Know-How and First Product Know-How*," Alkermes would receive at least 14% of NSP, 7% of any license revenues, and the ability to count sales of any follow-on drug toward the milestone payments in the License Agreement. *See* Clause 7.2 of the Follow-On Drug Agreement (emphasis added).

C. Additionally, Acorda specifically recognized the importance and value of the Elan Know-How in the Citizen Petition filed with the FDA in December 2016, particularly Alkermes's Impurity Know-How. Acorda stated:

> FDA appropriately redacted the identities of impurities and the methods used to qualify specific impurities because *that information includes trade secrets and/or confidential commercial information*. *See* 21 C.F.R. §§ 20.61 & 314.430(g). For the same reason, in this petition, Acorda has not identified impurities associated with AMPYRA® or the methods *that Acorda used* to identify and qualify each such impurity.[10]

(emphasis added). Acorda's claim in its Demand that the Elan Know-How no longer has value should not be credited when it also has highlighted the value of the Elan Know-How to the FDA.

D. In July 2018, the parties entered into a Consent to Sublicense in connection with Acorda's plan to launch an AG version of AMPYRA®. Acorda agreed to pay Alkermes a 10% royalty "as set forth in Article 5.6 of the Elan License Agreement" on the authorized generic product. The AG would have launched only if Acorda lost the patent case pending in the Federal Circuit and generic versions of

[10] Citizen Petition of Acorda Therapeutics, Inc., dated December 26, 2016, Page 3 n.14.

AMPYRA® entered the market – which is what happened in 2018. Thus, contemplating the exact circumstances that actually transpired, Acorda still agreed that the appropriate royalty was 10% of NSP. Acorda's entry into the Consent to Sublicense further confirms its recognition that the 10% royalty is appropriate and due at least on the Elan Know-How.

E. Finally, Acorda contractually reaffirmed its commitment to the License Agreement in August 15, 2018—two weeks *after* Alkermes's '938 patent expired. This alone should conclusively dispel any argument that Acorda accepted the royalty provisions of the License Agreement solely due to Alkermes's patent leverage. *See* Amended and Reinstated Consent to Sublicense, dated August 15, 2018, §§ 3(a), 9.

111. Indeed, if Acorda actually believed (as it asserts in its demand) that there was no ongoing Elan Patent Right after 2018, that the Know-How had no ongoing value, and that the supply price under the Supply Agreement was "higher . . . than it would have to pay otherwise" as it claims here, Acorda had an obvious remedy at its disposal: Acorda was free to terminate the License Agreement under Article 12.5.2.1 (*see supra* ¶ 60), to terminate the Supply Agreement (*see supra* ¶ 68), and seek supply from an alternative source. That Acorda has not chosen to terminate, and risk a lawsuit by Alkermes to recover lost royalties, suggests that Acorda does not itself believe the arguments it is advancing here asserting that the Elan Know-How has no value (and/or that there are no remaining Valid Claims).

112. Accordingly, even if it is determined that following the expiration of the '938 Patent in July 2018 there were no remaining Valid Claims, the continued existence of valuable Elan Know-How shows that the Elan Royalty Rate of 10% is permissible under *Brulotte* and *Kimble*, and that Acorda has no basis to argue that those royalties should not have been required. Any claim that 10% of NSP is not the fair market royalty for the Elan Know-How license, and is instead the product of some kind of coercion, is belied by Acorda's own conduct.

C. Even if the royalties were unenforceable under* Brulotte *after July 30, 2018, which Alkermes disputes, there is no basis in law for requiring Alkermes to refund royalties Acorda already paid.

113. Even if it were determined that there is a *Brulotte* violation, which Alkermes adamantly disputes, Acorda is not entitled to the refund it seeks for payments already made.

114. ***First***, the License Agreement specifically does not allow for such a refund demand. Article 5.8 states, "All payments received by [Alkermes] from Acorda under Article 5 shall be non-refundable," subject to the audit provision in Article 5.9.5.

115. Acorda cites Article 5.9.5 as a basis for requiring repayment, but that section provides no help for Acorda. The audit procedures in 5.9.5 are limited to assessing the correctness of actual royalty calculations; the audit right is designed as a double-check on the math of how much product actually was sold and the proper royalty calculation based on that

amount. Each party must give the other party's accountants access to its "books and records relating to the Product, solely for the purpose of verifying the accuracy and reasonable composition of the calculations hereunder for the calendar year then ended." It is a computational exercise, not one designed to second-guess the legal question of whether, notwithstanding the terms of the agreement, any royalties are actually due. This is why the access required under 5.9.5 is for the counter-parties' CPAs, not attorneys. Nothing in 5.9.5 contemplates, let alone requires, Alkermes to refund royalties actually paid by Acorda that properly compute the royalty due by multiplying the product sold by the applicable royalty rate.[11]

116. ***Second***, courts applying *Brulotte* have repeatedly held that it creates no requirement that royalties paid post expiration must be refunded, instead ruling that *Brulotte* only operates to bar efforts by the licensor to enforce the royalty prospectively. *See, e.g.*, *Zila v. Tinnell*, Order dated 4/22/04 (D.I. 172), Case No. CV-S-00-1345 (D. Nev.) (granting summary judgment against claim for refund of royalties under *Brulotte*), *aff'd*, 502 F.3d 1014, 1027 n.11 (9th Cir. 2007); *Tessera, Inc. v. Toshiba Corp.*, 2019 WL 5395158, at *6 (N.D. Cal. Oct. 22, 2019) (holding that *Brulotte* does not support an order to refund royalties already paid but "would only exclude [patentee's] affirmative claim for unpaid royalties due after expiration of a patent"); *Phillips Screw Co. v. Amtel, Inc*., 465 F.Supp. 3, 7 (D. Mass. 1978) (denying claim for refund of royalties under *Brulotte*).

117. ***Third***, New York's "voluntary payment doctrine" similarly bars any claim by Acorda for a refund. New York law requires a refund only if a party made payments based on a mistake of *fact*; it does not require repayment of funds made by a party due to its mistake of *law*. *See, e.g., Dillon v. U-A Columbia Cablevision of Westchester Inc.*, 292 A.D.2d 25, 27 (N.Y. Sup. Ct. App. Div. 2002), *aff'd* 100 N.Y.2d 525 (2003). Here, to the extent Acorda made any payments in error (which Alkermes disputes, because all the royalties Acorda paid were supported by valid and enforceable intellectual property rights), its error was solely one of law in failing to recognize that (according to Acorda's assertions) the royalty requirements had become unenforceable under *Brulotte* in 2018. New York law provides no remedy for Acorda in those circumstances; Acorda inflicted any purported injury on itself through its own lack of diligence.

118. Acorda has no plausible argument that it made a mistake of fact when it continued to pay royalties to Alkermes after the Federal Circuit decision 2018. Acorda paid exactly what the License Agreement on its face required, even assuming Acorda believed there were no Valid Claims as of July 30, 2018. Acorda cannot plausibly claim that it did not know about the Federal Circuit decision or the expiry of the '938 Patent. Among other things, Acorda was a party to the appeal decided by the Federal Circuit in September 2018, and the court's opinion specifically addressed both the invalidation of certain claims of some patents and the expiry of the '938 Patent. *Acorda*, 903 F.3d at 1313. Acorda plainly knew when the patents expired. At most, Acorda made a mistake of law, which it cannot attempt to recast

[11] Even if *Brulotte* renders the ongoing Know-How royalty in 5.6.2 unenforceable, it does not have any effect on the remaining provisions of the License Agreement, including the non-refundable provision in 5.8.

as a mistake of fact, and the law provides no remedy to relieve Acorda of the consequences of its own mistake of law.

119. Acorda's claim for a refund is particularly weak given that it is a sophisticated entity that was involved in drafting the License Agreement. *See, e.g.*, *Citicorp N. Am., Inc. v. Fifth Ave. 58/59 Acquisition Co., LLC*, 70 A.D.3d 408, 409 (N.Y. Sup. Ct. App. Div. 2010). Even if Acorda's patent misuse allegations were correct (which Alkermes denies), Acorda's continued payment of royalties without raising its *Brulotte* argument, and evidently without being aware of it, "demonstrate[s] a clear lack of diligence" by Acorda that further undermines its refund argument. *Citicorp*., 70 A.D.3d at 409; *see also Gimbel Bros. v. Brook Shopping Ctrs*., 118 A.D.2d 532, 535 (N.Y. Sup.Ct. App. Div. 1986). Acorda did not assert that the ongoing royalty payments were unenforceable under *Brulotte* until April 2020 at the earliest. Therefore, here, if any refund were due (which Alkermes disputes), the refund would apply at most to payments made after April 2020. For any payments prior to that, Acorda has no right to a refund to relieve itself from its own failure to investigate and assert its (purported) rights.[12]

120. ***Fourth***, Acorda is barred from asserting a claim for unjust enrichment or other equitable relief by the doctrine of unclean hands. If the licensing agreement is unenforceable, it is solely due to Acorda's improper assignment of the Unexpired Patents to itself. But for Acorda's wrongful removal of Sean Cunningham of Alkermes as an inventor of the '868 Application, and wrongful omission of him from the '559 Application, Alkermes would co-own the Unexpired Patents and could properly collect royalties on them under *Brulotte*. Equity does not permit Acorda to profit from its inequitable conduct.

121. A refund that violates the terms of the contract, the tenets of *Brulotte* and New York Law simply cannot be considered in equity and good conscience.

D. Acorda's antitrust claims have no merit.

122. Acorda's antitrust claims are completely baseless. Acorda asserts that Alkermes improperly perpetuated monopoly power in certain purported relevant markets by continuing to charge the royalties required by the License Agreement and the supply price required by the Supply Agreement after 2018. These arguments fail for several independent reasons, including but not limited to the following.

123. ***First***, the antitrust claims presuppose that Alkermes had no basis to continue charging royalties under the License Agreement after July 2018, and that the Supply Agreement

[12] Even if *some* refund were appropriate, it would not be the full amount of the royalties paid even after April 2020. The Elan Know-How has substantial value, and even if the royalty in 5.6.2 became unenforceable in 2018, Alkermes at a minimum has a claim against Acorda for the value of that know-how used for the product Alkermes sold Acorda. *See, e.g.*, *Kimble v. Marvel Enters. Inc*., 727 F.3d 856, 867 n.8 (9th Cir. 2013); *Span-Deck, Inc. v. Fab-Con, Inc.*, 677 F.2d 1237, 1247-49 (8th Cir. 1982); *Nordion Int'l, Inc. v. Medi-Physics, Inc.*, 1995 WL 519798, at *3 (N.D. Ill. Aug. 30, 1995) (collecting cases).

should have terminated at the same time. For all the reasons already discussed, Acorda is wrong, and so its antitrust claims fail without need for further scrutiny.

124. ***Second***, the antitrust claims depend on Acorda's ability to demonstrate that Alkermes had monopoly power in a properly defined relevant market after 2018. Acorda cannot do so. Acorda purports to define three separate relevant markets, though it never provides any economic analysis to support them. Neither the purported Technology Market nor the purported Supply Market (Demand ¶ 35) is a proper relevant market for antitrust purposes. Even the purported Product Market, limited to brand and generic versions of AMPYRA®, is too narrow; any proper product market would include other MS treatments such as Tecfidera and Copaxone. But even in the Product Market as alleged, Acorda concedes that there is substantial competition from the multiple generic entrants, which means Alkermes cannot have monopoly power. By itself, that kills Acorda's claims.

125. ***Third***, *having* monopoly power alone is not an antitrust violation. Acorda also would have to show that Alkermes acquired or maintained such power (assuming Alkermes had it) through exclusionary conduct. But charging (purportedly) high prices in the form of the continued license royalty and supply right is not exclusionary conduct, and Acorda alleges nothing else. *Verizon Comms. Inc. v. Trinko*, 540 U.S. 398, 407 (2004).

126. ***Fourth***, as already discussed, Alkermes *helped* Acorda compete with generic versions of AMPYRA®, rather than restraining Acorda. Alkermes licensed Acorda to sell an authorized generic version of AMPYRA® and manufactured the product that allowed Acorda to do so. Alkermes separately agreed to defer Acorda's royalty payments on brand AMPYRA® around the time of expected generic entry in 2018 to permit Acorda to develop its strategies for responding to marketplace developments. These are the actions of a company *creating* competition, not restraining it.

127. ***Fifth***, Alkermes cannot have wielded (let alone maintained) any purported monopoly over Acorda by charging royalties and the supply price because Acorda was free at all times to terminate the License Agreement and Supply Agreement. Of course, termination would cause Acorda to lose its licenses to Alkermes's intellectual property, and Acorda would face the risk of litigation from Alkermes, but Acorda asserts in these proceedings that Alkermes has no remaining rights, so – if Acorda's arguments are taken at face value – Acorda should have nothing to fear from such a suit. Acorda continues to obtain supply from Alkermes as a matter of Acorda's own choice. Perhaps Acorda cannot find anyone else willing to supply it, even though Alkermes worked with Acorda and succeeded in getting a second supplier of AMPYRA® qualified, but even if so, that problem cannot be attributed to Alkermes and would not amount to monopolization in any event.

128. ***Sixth***, Acorda cannot show harm to the competitive process itself, which is the essence of any antitrust claim. Acorda's real complaint is that the agreed-upon royalties and supply price it had to pay Alkermes purportedly caused Acorda to suffer lower sales and profits, because it lost sales to generics. To begin with, this claim is nonsensical: brand companies always lose sales to generics, because of the institutional features of the marketplace that drive generic substitution. But even if Acorda's allegations were true, and Acorda might have made incrementally more brand sales if it did not have to pay Alkermes, those facts

would not support an antitrust claim, because they only show purported harm to Acorda. "Because the antitrust laws protect competition, not competitors, a plaintiff must show more than its own business suffered; it must ultimately show that the challenged action harmed consumers." *MacDermid Printing Solutions LLC v. Cortron Corp*., 833 F.3d 172, 187 (2d Cir. 2016) (quotation marks omitted). The fact that consumers turned to lower-priced generic substitutes in place of brand AMPYRA® demonstrates competition in action, not anticompetitive restraints harming consumers.

129. Acorda also suggests that the purportedly higher prices for AMPYRA® caused by Alkermes continuing to charge the license royalties and supply price also somehow led to improperly elevated generic prices as well. The evidence will not support that theory, and it is contrary to how pharmaceutical markets actually work. In general, brand prices exert little to no effect on generic prices. Generic companies price their products based on the number of generic competitors they face and the prices offered by those generic competitors. Brand prices do not factor into that equation. Therefore, even if all the other allegations about prices of brand AMPYRA® were true, none of them would show harm to *competition*, because generic competition has been running at full throttle since 2018.

E. Acorda has no viable claim for breach of implied covenant.

130. Acorda argues that Alkermes breached the implied covenant of good faith and fair dealing "by retaining and improperly refusing to return to Acorda the excess royalty payments which Acorda paid to Alkermes under the License Agreement," (Demand ¶ 78) thereby purportedly depriving and destroying Acorda of the benefits of the agreements. This argument, too, fails at the outset.

131. Under governing New York law, the covenant of good faith and fair dealing only applies "in aid and furtherance of other terms of the agreement of the parties. No obligation can be implied, however, which would be inconsistent with other terms of the contractual relationship." *Murphy v. Am. Home Prods. Corp*., 58 N.Y.2d 293, 304 (1983).

132. Here, the implied duty to a refund that Acorda seeks to impose by invoking the implied covenant doctrine would fly in the face of the express terms of the agreements, and Acorda's claim therefore fails. The License Agreement expressly states that the royalty will be 10%, even when there is no Valid Claim, unless and until the three conditions specified in Article 5.6.2 occur (which indisputably has not happened), meaning the 10% royalty has remained due at all times. Additionally, as discussed above, the contract expressly states that payments made by Acorda to Alkermes are not refundable. *See* Ex. A, Article 5.8. And Article 5.9.5 has no bearing here, as it is limited to uncovering accounting errors and does not apply to require refunds of amounts paid under a mistake of law, as discussed above. Therefore, because the agreements expressly required Acorda to pay the royalties and expressly declared that royalties paid will not be refundable, Acorda cannot assert a claim under the implied covenant based on the lack of a refund as a matter of law.

133. Moreover, Alkermes cannot be said to have deprived Acorda of the benefits of the agreements when both Alkermes and Acorda have followed the agreements to the letter.

Acorda got exactly the agreements and benefits for which it bargained: licenses to Alkermes's intellectual property and supply of product manufactured by Alkermes at the rates Acorda had agreed to pay.

F. Acorda cannot recover attorneys' fees.

134. Acorda and Alkermes expressly waived any claim for attorneys' fees in connection with arbitration in the License Agreement. Even if Acorda were to prevail in its Demand, therefore, it could not recover attorneys' fees or other fees related to these proceedings.

CONCLUSION

135. For the reasons stated above, Acorda's demand is without merit. Alkermes respectfully requests that the Tribunal issue an award denying Acorda's claims against Alkermes in their entirety.

COUNTERCLAIMS

A. Counterclaim I: Correction of Inventorship Pursuant to 35 U.S.C. § 256.

136. Alkermes incorporates paragraphs 1-135 as if fully set forth herein.

137. Title 35, Section 256(a) of the United States Code provides that the Director of the United States Patent and Trademark Office may correct the inventorship of a patent on application of all the relevant parties and assignees.

138. Title 35, Section 256(b) of the United States Code provides that a court may order correction of the inventorship of a patent after notice and hearing.

139. Title 35, Section 294 of the United States Code provides that disputes concerning the validity of a patent may be subject to arbitration. Inventorship is an issue going to the validity of a patent.

140. As explained *supra* in paragraphs 87-101, Sean Cunningham, Seamus Mulligan and/or Michael Myers of Alkermes conceived, or contributed to the conception of, the subject matter disclosed and claimed in the Unexpired Patents.

141. Sean Cunningham, Seamus Mulligan and/or Michael Myers are therefore at least joint inventors of the subject matter disclosed and claimed in the Unexpired Patents.

142. Because Sean Cunningham, Seamus Mulligan and/or Michael Myers are at least joint inventors of the subject matter disclosed and claimed in the Unexpired Patents and because Sean Cunningham, Seamus Mulligan and Michael Myers were Alkermes employees at the time of invention, Alkermes jointly owns the Unexpired Patents and maintains joint equitable title in the Unexpired Patents.

143. Accordingly, Alkermes seeks a finding that Sean Cunningham, Seamus Mulligan and/or Michael Myers are joint inventors of the Unexpired Patents, and an order that Acorda apply

to the Director of the United States Patent and Trademark Office to correct the inventorship of the Unexpired Patents so that they conform to this Tribunal's award.

B. Counterclaim II: Declaratory Judgment that the Unexpired Patents Must Be Assigned to Alkermes.

144. Alkermes incorporates paragraphs 1-143 as if fully set forth herein.

145. As explained *supra* in paragraphs 84-102, Sean Cunningham, Seamus Mulligan and/or Michael Myers of Alkermes conceived, or contributed to the conception of, the subject matter disclosed and claimed in the Unexpired Patents.

146. Because of the contributions of Sean Cunningham, Seamus Mulligan and/or Michael Myers to the invention of the Unexpired Patents, Alkermes has an ownership interest in the Unexpired Patents.

147. Therefore, all of the Unexpired Patents are Elan Patent Rights by virtue of the "interest" Alkermes has in their conception or reduction to practice. Ex. A, Article 1.1.

148. Furthermore, the '826 patent and '685 patent are Elan Patent Rights for the additional reason that they are "patent[s] issuing" on "patent applications . . . filed[or] owned . . . by [Alkermes] . . . which would be infringed by the manufacture, use or sale of the Product . . . ." Ex. A, Article 1.1.

149. As Elan Patent Rights, the Unexpired Patents constitute part of the Elan Intellectual Property. Ex. A, Article 1.1.

150. The Parties agreed that "Acorda Patent Rights shall exclude Elan Intellectual Property." Ex. A, Article 1.1.

151. Alkermes thus seeks a declaration that Acorda has no right to the Unexpired Patents, and that Acorda must assign the Unexpired Patents to Alkermes.

PRAYER FOR RELIEF

152. For the reasons stated above, Alkermes respectfully requests that the Tribunal issue an award:

(a) Denying all relief sought by Acorda;

(b) Declaring that Sean Cunningham, Seamus Mulligan and/or Michael Myers are joint inventors of the Unexpired Patents;

(c) Ordering Acorda to seek correction of the inventorship of the Unexpired Patents;

(d) Declaring that Acorda must assign the Unexpired Patents to Alkermes; and

(e) Granting Acorda such further and additional relief as may be deemed just and proper.